07-21-03 4 Supp Appeal Brief

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Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re:	**Application Serial No.:**	**09/428,035**
	Confirmation No.:	**4121**
	Appellants:	**McGrady, et al.**
	Title:	**Method of Dispensing and Tracking the Giving of Medical Items to Patients**
	Docket No.:	**D-1123**

Sir:

Please find enclosed the Supplemental Appeal Brief of Appellants pursuant to 37 C.F.R. § 1.192 in triplicate, in response to the Action dated April 22, 2003, for filing in the above-referenced application.

No fee is deemed required. However, the Commissioner is authorized to charge any necessary fee associated with the filing of the Supplemental Appeal Brief and any other fee due to Deposit Account 10-0637.

Very truly yours,

Ralph E. Jocke
Reg. No. 31,029

REJ:tcp

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D-1123

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of	**McGrady, et al.**	)	
Serial No.:	**09/428,035**	)	Art Unit: **3626**
Confirm. No.:	**4121**	)	
Filed:	**October 27, 1999**	)	Patent Examiner: **Milan S. Kapadia**
Title:	**Method of Dispensing and Tracking the Giving of Medical Items to Patients**	)	

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SUPPLEMENTAL BRIEF OF APPELLANTS PURSUANT TO 37 C.F.R. § 1.192

Sir:

The Appellants hereby respectfully request reinstatement of the appeal pursuant to 37 C.F.R. § 1.193(b)(2). The Appellants hereby submit their Supplemental Appeal Brief pursuant to 37 C.F.R. § 1.192, in triplicate, concerning the above-referenced Application.

REAL PARTY IN INTEREST

The Assignee of all right, title and interest to the above-referenced Application is MedSelect Inc., a Delaware corporation.

RELATED APPEALS AND INTERFERENCES

Appellants believe that there are no related appeals or interferences pertaining to this matter.

STATUS OF CLAIMS

Claims 1-28 are pending in the Application.

Claim 22 was objected to because of an alleged informality. Appellants respectfully traverse the claim objection. A traversal of the claim objection was submitted by the Appellants in a separate response to the Office on July 2, 2003.

Claims 4, 6-8, 11-13, 16-18, and 22-27 were rejected pursuant to 35 U.S.C. § 102(b) as being anticipated by Gombrich, et al. (US 4,857,716) ("Gombrich").

Claims 1-3, 5, 14-15, and 28 were rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Gombrich in view of Moulding, Jr. et al. (US 4,604,847) ("Moulding").

Claims 9-10 and 19-21 were rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Gombrich.

These rejections were the only rejections present in the Office Action ("Action") dated April 22, 2003, which was made Final. Appellants appeal the rejections of the claims, inclusive.

Additional Comments

Appellants filed an Appeal Brief on January 27, 2003. It is unclear how, in response to the Appeal Brief filing, a new grounds of rejection could be applied and made final. Even the Action admits that the grounds of rejection is new (page 15, last line). The Offices' premature final rejection is troubling, and reflective of all the rejections on appeal. In spite of the Action's premature final rejection, Appellants desire to proceed with their appeal to prevent even further unnecessary prosecution delay by the Office.

STATUS OF AMENDMENTS

A final rejection was made April 22, 2003. Appellants submitted a subsequent amendment on July 2, 2003.

Appellants reserve all rights regarding the Office's response to their after final amendment submitted on July 2, 2003, including the filing of another Supplemental Appeal Brief.

SUMMARY OF INVENTION

Overview of the Invention

An exemplary form of the invention is directed to apparatus and method which permits accurate monitoring of medical inventories, dispensing of medical items, and correlating the use of medical items with the patient whose treatment has included their use.

A generated report (388, 654) includes the names of patients who may receive medical items, as well as machine readable indicia which corresponds to each patient. The report further includes the medical items that have been prescribed for the patients, as well as machine readable indicia representative thereof (page 90, line 22 to page 91, line 3; page 129, lines 7-8). Reports can be generated responsive to data stored in a data store (326) in response to operation of a system computer (324). Particularly note Figures 40 and 62, and the descriptions thereof.

The reports, which include the information concerning patients and medical items that have been prescribed for the patients, may also include other information such as the location of each patient and the times or frequency that particular medical items have been prescribed for use in the treatment of the patients (page 129, lines 12-16).

A reading device (348, 660) may be used to read report indicia representative of a patient and/or a medical item prescribed for the patient. Medication may be dispensed from a dispenser (346) in response to the reading of indicia corresponding to the medication from a report (page 94, lines 7-18; page 130, lines 1-8). By reading such indicia the reading device also causes data to be stored in the data store representative that a particular medical item has been taken for use by a patient.

The ability to dispense and access medications based on machine readable indicia from reports increases the speed at which items may be dispensed and the information recorded for storage in the appropriate data store of the system. Thus, a report can be used in carrying out functions such as dispensing and tracking activities.

CONCISE STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

The questions presented in this appeal are:

1). Whether Appellants' claims 4, 6-8, 11-13, 16-18, and 22-27 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by Gombrich.

2). Whether Appellants' claims 1-3, 5, 14-15, and 28 are unpatentable under 35 U.S.C. § 103(a) over Gombrich in view of Moulding.

3). Whether Appellants' claims 9-10 and 19-21 are unpatentable under 35 U.S.C. § 103(a) over Gombrich.

GROUPING OF CLAIMS

No groups of claims stand or fall together. Every claim recites additional features of the invention which distinguishes the claim over every other pending claim.

Each of Appellants' claims recites at least one element or combination of elements not found or suggested in the applied references, which patentably distinguishes the claims.

The pending claims include six independent claims (claims 1, 4, 16, 19, 20, and 26). Claims 2-3, 5, and 14-15 depend from claim 1. Claims 6-13 depend from claim 4. Claims 17-18, 22-25, and 28 depend from claim 16. Claim 21 depends from claim 19. Claim 27 depends from claim 26. All pending claims 1-28 are reproduced in the Appendix.

ARGUMENT

The Applicable Legal Standards

Anticipation pursuant to 35 U.S.C. § 102 requires that a single prior art reference contain all the elements of the claimed invention arranged in the manner recited in the claim. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983).

Anticipation under 35 U.S.C. § 102 requires in a single prior art disclosure, each and every element of the claimed invention arranged in a manner such that the reference would literally infringe the claims at issue if made later in time. *Lewmar Marine, Inc. v. Barient, Inc.*, 822 F.2d 744, 747, 3 USPQ2d 1766, 1768 (Fed. Cir. 1987).

Anticipation by inherency requires that the Patent Office establish that persons skilled in the art would recognize that the missing element is necessarily present in the reference. To establish inherency the Office must prove through citation to prior art that the feature alleged to be inherent is "necessarily present" in a cited reference. Inherency may not be established based on probabilities or possibilities. It is plainly improper to reject a claim on the basis of 35 U.S.C. § 102 based merely on the possibility that a particular prior art disclosure could or might be used or operated in the manner recited in the claim. *In re Robertson*, 169 F.3d 743, 49 U.S.P.Q. 2d 1949 (Fed. Cir. 1999).

Before a claim may be rejected on the basis of obviousness pursuant to 35 U.S.C. § 103, the Patent Office bears the burden of establishing that all the recited features of the claim are known in the prior art. This is known as *prima facie* obviousness. To establish *prima facie* obviousness, it must be shown that all the elements and relationships recited in the claim are

known in the prior art. If the Office does not produce a *prima facie* case, then the Appellants are under no obligation to submit evidence of nonobviousness. MPEP § 2142.

The teaching, suggestion, or motivation to combine the features in prior art references must be clearly and particularly identified in such prior art to support a rejection on the basis of obviousness. It is not sufficient to offer a broad range of sources and make conclusory statements. *In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

Even if all of the features recited in the claim are known in the prior art, it is still not proper to reject a claim on the basis of obviousness unless there is a specific teaching, suggestion, or motivation in the prior art to produce the claimed combination. *Panduit Corp. v. Denison Mfg. Co.*, 810 F.2d 1561, 1568, 1 USPQ2d 1593 (Fed. Cir. 1987). *In re Newell*, 891 F.2d 899, 901, 902, 13 USPQ2d 1248, 1250 (Fed. Cir. 1989).

The evidence of record must teach or suggest the recited features. An assertion of basic knowledge and common sense not based on any evidence in the record lacks substantial evidence support. *In re Zurko*, 258 F.3d 1379, 59 USPQ2d 1693 (Fed. Cir. 2001).

A determination of patentability must be based on evidence of record. *In re Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002).

It is respectfully submitted that the Action from which this appeal is taken does not meet these burdens.

The Gombrich Reference

Gombrich is directed to a patient identification and verification system. The patient identification system includes a computer system (42) having terminals (45). The terminals

include a keyboard and a display for input of data to and output of data from the computer system (col. 8, lines 23-26). The patient identification system further includes a bar code reading device (48). The reading device is utilized to read a bar code (50) on a patient's identification bracelet (52); a bar code (51) on an item relating to a specific patient, such as the patient's medical chart; and a bar code (49) on medical item which can be correlated to a specific patient.

In operation of administering a medical item, a nurse first reads her identifying bar code (col. 15, lines 9-16). Next the nurse reads the patient's bracelet bar code, then the bar code on the medical item is read. Checks are performed at the computer system (42) to ensure that the medical item properly corresponds to the identified patient. If the medical item bar code matches the patient's bar code and the pharmacy drug code, then a green status light will prompt the nurse to proceed (col. 15, lines 58-65). However, if there is a discrepancy, then a red status light will flash.

The Moulding Reference

Moulding is directed to a method of opening a package with a cutting machine. A medicine package is constructed so that it is difficult to open without using the cutting machine. The package includes machine readable code thereon. The code includes information on the medicine contained in the package. The cutting machine includes means for reading machine readable code on the package. The cutting machine includes a computer having stored therein acceptable cutting conditions (e.g., patient, needed medicine, time). If all of the conditions are not satisfied upon reading the package code, then the computer will not permit the package to be severed by the cutting machine (col. 1, line 58 to col. 2, line 23).

(iii) 35 U.S.C. § 102

The Pending Claims Are Not Anticipated By Gombrich

In the Action claims 4, 6-8, 11-13, 16-18, and 22-27 were rejected under 35 U.S.C. § 102(b) as being anticipated by Gombrich. These rejections are respectfully traversed. The Appellants respectfully disagree with the Action's interpretation and application of Gombrich.

The Office previously relied on Gombrich in view of Moulding for the rejections of claims 6-8, 11-13, 16-18, 22-25, and 27 (i.e., Office Action dated August 5, 2002). Thus, by inference, the Office has already admitted that Gombrich cannot anticipate these claims.

The Office interprets many features in Gombrich as being recited features. However, anticipation pursuant to 35 U.S.C. § 102 requires that Gombrich itself teach each of the claimed features in the manner recited. The rejections cannot be based on the Office's biased interpretations, but rather what Gombrich actually teaches. Furthermore, to establish anticipation by inherency the Office must prove (through citation to prior art) that persons skilled in the art would recognize that the missing element is necessarily present in Gombrich. Inherency may not be established based on the Office's hindsight interpretations, only on what the prior art actually teaches. Appellants respectfully submit that the 35 U.S.C. § 102 rejections are not based on actual prior art teachings, and should therefore be withdrawn.

Many of Appellants' remarks in support of the patentability of the claims can be found in more detail in Appellants' remarks regarding claim 1. Thus, Appellants' request that their corresponding applicable claim 1 remarks also be considered.

Claim 4

Gombrich does not teach the recited features, relationships, and steps. For example, Gombrich does not teach inputting data representative of giving the medical item to the patient to a portable terminal, storing data representative of the giving of the medical item in the portable terminal, and transferring data representative of the giving of the medical item from the portable terminal to the computer, where the computer is operative to include in the data store, data representative of the medical item having been given to the patient (part e).

The Action (on page 4) alleges that Gombrich teaches the recited features at col. 11, lines 4-44. Appellants respectfully disagree. The relied upon section of Gombrich refers to a bar code reader (48). The bar code reader (48) is used to read bar codes (col. 8, lines 56-58). The bar code reader does not constitute the recited portable terminal. The bar code reader is not a portable terminal capable of receiving inputted data representative of the giving of a medical item to a patient. Nor does the bar code reader store data representative of the giving of the medical item therein. Nor is the bar code reader capable of transferring data representative of the giving of the medical item, from the bar code reader to a computer so that the computer is operative to include in a data store the data representative of the medical item having been given to the patient. Where does Gombrich teach that the bar code reader (48) stores information regarding the giving of a medical item to a patient, and then transfers this information to a computer/data store? Nor does Gombrich teach the other recited steps.

Appellants' Specification discloses an exemplary portable terminal (e.g., 662) and a bar code reader (e.g., 104). Gombrich discloses a terminal (45) and a bar code reader (48). That is, Gombrich distinguishes a terminal from a bar code reader. Further note Gombrich's distinction

of a terminal (45) from a bar code reader (48) in Gombrich's Figure 1. The Office's attempt to redefine (i.e., modify or teach away from) an explicit teaching of Gombrich is legally improper (and requires an action beyond anticipation). Furthermore, if Gombrich's "bar code reader" (48) constitutes a "terminal" as the Office alleges, then what does Gombrich's terminal (45) constitute?

The Action's reliance (Action page 18) upon the upon Microsoft Computer Dictionary (5th edition) to define "terminal" is noted. However, the Microsoft Dictionary, which has a 2002 publication date, does not constitute prior art against Appellants claimed invention and must be disregarded. However, it should be noted that the term "bar code reader" is also in the Microsoft Dictionary. Thus, the Microsoft Dictionary (if it constituted prior art), like Gombrich, would also distinguish a "terminal" from a "bar code reader".

The Office also alleges (at Action page 3) that Gombrich teaches "printing on a sheet of bar code labels, patient specific bar code identifiers and the patient's name", which has been interpreted by the Office as a form of "report" generation. The Action relies on Gombrich at col. 12, lines 66-67, col. 13, lines 1-2; and Figure 4.

Appellants respectfully disagree. Gombrich does not teach part (b) of claim 4 (i.e., "generating a report, wherein the report includes machine readable indicia corresponding to at least one of the patients"). The Office's new definition of "report" does not fall within the context of "report" as determined by one of ordinary skill in the art, conventional definition, the Microsoft Dictionary (if it constituted prior art), or Appellants' disclosure. Gombrich's Figure 4 is not a report. Generating a report was previously discussed in the "Overview of the Invention"

section, and a report (388, 654) is shown in Figures 40 and 62. Thus, Gombrich does not anticipate claim 4.

Furthermore, Gombrich discloses that the scanning of bar codes may not result in "the giving of a medical item to a patient". For example, scanned bar codes can result in a discrepancy (red light status) (e.g., col. 15, lines 58-65). Thus, Gombrich does not teach "storing" or "transferring" data representative of "the giving" of a medical item to a patient (i.e., claim 4, part (e)).

The rejection of claim 4 is based on alleged teachings of Gombrich, not factual showings of what Gombrich actually teaches. That is, the record lacks substantial evidence support. *In re Zurko*, supra. Gombrich does not explicitly or inherently teach the recited method. There is no evidence that a teaching of inputting data representative of giving a medical item to a patient, to a portable terminal, storing data representative of the giving of the medical item in the portable terminal, and transferring data representative of the giving of the medical item from the portable terminal to a computer is "necessarily present" in Gombrich.

To establish inherency the Office must prove through citation to prior art that the feature alleged to be inherent is "necessarily present" in a cited reference. Inherency may not be established based on probabilities or possibilities. *In re Robertson*, supra. The Appellants respectfully submit that the Office has not proved that the recited steps are "necessarily present" in the Gombrich reference. Gombrich does not anticipate claim 4. Thus, it is respectfully submitted that the 35 U.S.C. § 102(b) rejection should be withdrawn.

Claim 6

Claim 6 depends from claim 4. Gombrich further does not teach reading machine readable indicia with a terminal reading device in the manner recited.

Claim 7

Claim 7 depends from claim 6. Gombrich further does not teach reading machine readable indicia on a patient associated item with a terminal reading device in the manner recited.

Claim 8

Claim 8 depends from claim 7. Gombrich further does not teach reading machine readable indicia on a patient band with a terminal reading device in the manner recited.

Claim 11

Claim 11 depends from claim 7. Gombrich further does not teach generating a prescribed item report, wherein the prescribed item report includes machine readable indicia corresponding to at least one medical item prescribed for the patient, and reading the machine readable indicia corresponding to the medical item from the prescribed item report.

Claim 12

Claim 12 depends from claim 7. Gombrich further does not teach a report including both machine readable indicia corresponding to at least one of the patients and machine readable indicia corresponding to at least one medical item prescribed for the patient. The Action admits (on page 12, first paragraph) that Gombrich does not teach the recited feature. The Action further admits (on page 17, last paragraph) that the combined teachings of Gombrich and Moulding are required for the recited feature. It follows that Gombrich does not teach reading machine readable indicia on the report with a terminal reading device. Furthermore, it is unclear

how a bar code label can constitute both a report and machine readable indicia in the report. Gombrich cannot anticipate claim 12.

Claim 13

Claim 13 depends from claim 4. Gombrich further does not teach placing a portable terminal in connection with a docking port, wherein data representative of the giving of a medical item is transferred from the portable terminal to a computer through the docking port.

Claim 16

Gombrich does not teach the recited features, relationships, and steps. Note Appellants' remarks in support of the patentability of claim 1.

As previously discussed, Gombrich does not teach "generating a report". Furthermore, Gombrich does not teach "generating a report including machine readable indicia indicative of a medical item prescribed for a patient, wherein the report further includes information indicative of the patient" (i.e., step c).

Additionally, Gombrich does not teach "reading with a reading device the machine readable indicia on the report" (i.e., step e). Even the Office Action dated August 5, 2002 (on page 5, part D) admitted that Gombrich failed to teach the recited feature.

The Action alleges that Gombrich teaches "scanning the drug identifier bar code" on a drug package (col. 14, lines 22-24) and also teaches a "report" (as discussed in the rejection of claim 1). Appellants respectfully disagree. As previously discussed, Gombrich does not teach "generating a report". Additionally, a bar code label on a drug package would not constitute the recited report. Even if Gombrich had a bar code on a drug package, there is no evidence that the drug package <u>further</u> includes information indicative of the patient. Gombrich does not teach a

report including both machine readable indicia indicative of a medical item prescribed for a patient and further information indicative of the patient. Gombrich's drug packages do not contain patient information. Gombrich's drug packages are generic and are not assigned to any particular patient. In Gombrich the patient' identification information is on the patient's prescription (col. 13, lines 57-59). The Action admits (and relies on) such teaching in Gombrich in the allegation of step (d).

In Gombrich the patient's prescription (with patient identification information) is separate from the drug package. Gombrich does not teach a report including both the patient's prescription and the drug package. It follows that Gombrich does not teach "generating a report including machine readable indicia indicative of a medical item prescribed for a patient, wherein the report further includes information indicative of the patient". It further follows that Gombrich does not teach "reading with a reading device the machine readable indicia on the report". Gombrich does not anticipate claim 16. Thus, it is respectfully submitted that the 35 U.S.C. § 102(b) rejection should be withdrawn.

Claim 17

Claim 17 depends from claim 16. Gombrich further does not teach "including on the report, machine readable indicia indicative of the one patient", and "reading with a reading device the machine readable indicia indicative of the one patient on the report". As previously discussed, Gombrich does not teach generating a report including both machine readable indicia indicative of a medical item prescribed for a patient and machine readable indicia indicative of the patient. Nor does Gombrich does not teach step (d). As to "reading with a reading device the machine readable indicia indicative of the one patient on the report", even the Office Action

dated August 5, 2002 (on page 6, part E) admitted that Gombrich failed to teach the feature. It follows that Gombrich cannot anticipate claim 17.

Claim 18

Claim 18 depends from claim 16. Gombrich further does not teach storing data representative that a medical item has been used in the medical treatment of a patient in a portable terminal, and transferring the data from the portable terminal to a computer. As previously discussed, Gombrich does not teach storing data indicative that a medical item has been used.

Claim 22

Claim 22 depends from claim 16. Gombrich further does not teach storing data in a portable terminal adjacent a bedside of the patient indicative that a medical item has been used in the medical treatment of the patient. Gombrich also does not teach placing the portable terminal in operative connection with a computer, where information indicative of the use of the at least one medical item is passed from the portable terminal to the computer in the manner recited.

Claim 23

Claim 23 depends from claim 22. Gombrich further does not teach that data indicative that a medical item has been given to the patient is stored in a portable terminal responsive to reading the machine readable indicia on a patient associated item in the manner recited.

Claim 24

Claim 24 depends from claim 23. Gombrich further does not teach that a patient associated item from which a machine readable indicia is read comprises at least one of a band worn by the patient, a bed label, or a chart in the manner recited.

Claim 25

Claim 24 depends from claim 16. Gombrich further does not teach storing data in a bedside terminal adjacent a patient, where the data is indicative that a medical item has been used in the medical treatment of the patient.

Claim 26

Gombrich does not teach the recited features, relationships, and steps. For example, Gombrich does not teach storing data in a bedside terminal positioned in generally fixed relation adjacent a bedside area of a patient, indicative that the one medical item has been used in the medical treatment of the one patient.

Regarding part (g), the Action alleges that Gombrich's terminals (45) can be located at a nurse's station. The Action interprets a nurse's station as being positioned in generally fixed relation adjacent a bedside area of a patient. The Action relies on Gombrich at col. 8, lines 23-28.

Appellants respectfully disagree. The claim at part (g) recites "storing data in a bedside terminal". Gombrich does not teach positioning a terminal at a patient's bedside. Nor does Gombrich teach having a bedside terminal positioned in generally fixed relation adjacent a bedside area of a patient. One skilled in the art would recognize that a nurse's station is not adjacent a patient's bedside. One skilled in the art would further recognize that a terminal at a nurse's station would not constitute a terminal at a patient's bedside.

Furthermore, the relied on section of Gombrich indicates that the terminal (45) may be located in a non public (e.g., non patient) secured area, such as the pharmacy, laboratory, supply room, in X-ray, in radiology, billing department, or at a nurses' station. There is no teaching or

suggestion of a bedside terminal positioned in generally fixed relation adjacent a bedside area of a patient, or of storing data in the bedside terminal indicative that a medical item has been used in the medical treatment of that bedside area patient. Contrarily, Gombrich teaches away from having a fixed bedside terminal. For example, Gombrich's Figure 1 explicitly teaches keeping the terminals (45) outside of patients' rooms.

Regarding (e), the Action alleges that Gombrich's "being approved" constitutes the recited "taken for use". Appellants respectfully disagree. The claim at (e) recites storing data that the medical item has been taken for use by the one patient. Gombrich does not teach (e). The Action relies on Gombrich at col. 14, lines 22-25. However, the relied upon section relates to a pharmacist entering a drug prescription approved for a patient. The relied upon section does not relate to storing data indicating that a medical item has been taken for use by the patient. Rather, in Gombrich the pharmacist (not the patient) still has the medical item.

Gombrich does not anticipate claim 26. Thus, it is respectfully submitted that the 35 U.S.C. § 102(b) rejection should be withdrawn.

Claim 27

Claim 27 depends from claim 26. Gombrich further does not teach storing data in a portable terminal adjacent a bedside of a patient indicative that a medical item has been used in the medical treatment of the one patient, and passing the data between the portable terminal and a bedside terminal. Gombrich does not teach a portable terminal and a bedside terminal in the manner recited.

(iv) 35 U.S.C. § 103

The Appellants respectfully submit that the attempts to combine the teachings of the references are clearly attempts at hindsight reconstruction of Appellants' claimed invention, which is legally impermissible and does not constitute a valid basis for a finding of obviousness. *In re Fritch*, 22 USPQ2d 1780 (Fed. Cir. 1992). The rejections, which lack the necessary evidence and rationale, are based on knowledge gleaned only from Appellants' disclosure. It follows that it would not have been obvious to have modified the references in the manner alleged. Furthermore, without a motivation to combine, which is the current situation, a rejection based on a *prima facie* case of obviousness is improper (MPEP § 2143.01).

Appellants traverse the rejections on the grounds that Appellants' claims recite features, relationships, and steps which are neither disclosed nor suggested in the cited art, and because there is no teaching, suggestion, or motivation cited so as to produce Appellants' invention. The features and relationships recited in Appellants' claims patentably distinguish over the applied references. Nor would it have been obvious to one having ordinary skill in the art to have combined the teachings of the references to have produced the recited invention.

The evidence of record does not teach or suggest the recited features. *In re Zurko*, supra. The Office does not factually support any *prima facie* conclusion of obviousness. If the Office does not produce a *prima facie* case, which is the current situation, then the Appellants are under no obligation to submit evidence of nonobviousness (MPEP § 2142). Thus, it is respectfully submitted that the 35 U.S.C. § 103(a) rejections are improper and should be withdrawn.

The Pending Claims Are Not Obvious Over
Gombrich in view of Moulding

Claims 1-3, 5, 14-15, and 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Gombrich in view of Moulding. These rejections are respectfully traversed.

Claim 1

Neither Gombrich nor Moulding, taken alone or in combination, disclose or suggest the recited features, relationships, and steps. Neither reference, taken alone or in combination, discloses or suggests "generating a report, wherein the report includes machine readable indicia corresponding to at least one of the patients and machine readable indicia corresponding to at least one item prescribed for the patient" (step b).

The Action alleges that Gombrich teaches "printing on a sheet of bar code labels, patient specific bar code identifiers and the patient's name". The Action relies on Gombrich at col. 12, lines 66-67, col. 13, lines 1-2; and Figure 4. The Action further alleges that Gombrich teaching is interpreted as a form of report generation. Appellants respectfully disagree.

The Appellants disagree with the Office's interpretation of Gombrich. Note Appellants' remarks in support of the patentability of claim 4. As previously discussed, Gombrich does not teach or suggest "generating a report". The Office's interpretation of "report" does not fall within the context of "report" as determined by one of ordinary skill in the art, conventional definition, the Microsoft Dictionary (if it constituted prior art), or Appellants' disclosure. Gombrich's Figure 4 is not a report. Generating a report was previously discussed in the "Overview of the Invention" section, and a report (388, 654) is shown in Figures 40 and 62.

Nevertheless, even if it were somehow possible (which it isn't) to interpret Gombrich's separate bar codes as separate reports, Gombrich would still not teach or suggest generating a

report, where the report includes both machine readable indicia corresponding to at least one of the patients and machine readable indicia corresponding to at least one item prescribed for the patient. Even the Action (on page 10) admits that Gombrich does not teach or suggest "a report that includes patient identifiers and machine-readable indicia corresponding to at least one item prescribed for the patient".

Moulding cannot overcome the admitted and previously discussed deficiencies of Gombrich as it does not disclose or suggest the recited features which are not found in Gombrich. The Action relies on the language "means for recording" in Moulding at col. 2, lines 16-22. The Action states that "the examiner interprets" this language as a form of "generating a report". Appellants respectfully disagree.

Moulding is directed to a method of opening a package. Moulding is non analogous art. Moulding also does not teach or suggest "generating a report" in the manner recited. The relied upon section of Moulding states that a "cutting machine may be provided with means for recording the characteristics of the medicine in the package as indicated by the machine readable code, the time when the code was read, the identity of the patient, etc." Moulding at col. 1, lines 64-65 also states that the "cutting machine includes a means for reading the machine readable code".

Moulding's means for recording is directed to recording the characteristics of already read machine readable code. Apparently, the characteristics are "recorded" in the memory of a computer (col. 9, lines 22-23 and 35-39; col. 2, line 6). However, in Moulding it is the package which has the machine readable code. Moulding does not generate a report that includes any "machine readable indicia". Nor does Moulding generate a report including machine readable

indicia corresponding to at least one of the patients. Nor does Moulding generate a report including machine readable indicia corresponding to at least one item prescribed for the patient. It follows that Moulding does not generate a report including both readable indicia corresponding to at least one of the patients and machine readable indicia corresponding to at least one item prescribed for the patient.

Additionally, neither Gombrich nor Moulding, taken alone or in combination, disclose or suggest "reading the machine readable indicia on the report corresponding to a patient with a reading device".

The record lacks substantial evidence support. *In re Zurko*, supra. Nor does Gombrich have any need of the teachings of Moulding. It is unclear how Gombrich could be modified by the teachings of Moulding to have produced the recited invention. The Action is also devoid of any teaching, suggestion, or motivation for combining the references to have produced the recited invention.

Additionally, even if it were somehow possible (which it isn't) to combine the references, the resultant combination would not have been obvious because the prior art does not suggest the desirability of the combination (MPEP § 2143.01). Nevertheless, even if it were somehow possible (which it isn't) to combine the references, the resultant combination still would not have produced the recited invention. Neither Gombrich nor Moulding, taken alone or in combination, disclose or suggest the recited features and relationships. The Office has not established a *prima facie* showing of obviousness.

Claim 2

Claim 2 depends from claim 1. Neither of the applied references, taken alone or in combination, teach or suggest reading machine readable indicia corresponding to a medical item with a reading device, especially where the machine readable indicia corresponding to the medical item is included in a report with machine readable indicia corresponding to at least one of the patients.

The Action alleges that scanning a drug identifier bar code (col. 14, lines 22-25) constitutes recited step (d). Appellants respectfully disagree. The relied upon section of Gombrich does not teach or suggest reading machine readable indicia (on a report) corresponding to the medical item with the reading device. Nevertheless, neither Gombrich nor Moulding, taken alone or in combination, disclose or suggest a report including both readable indicia corresponding to at least one of the patients and machine readable indicia corresponding to at least one item prescribed for the patient. Nor has the Office established a *prima facie* showing of obviousness.

Claim 3

Claim 3 depends from claim 1. Neither of the applied references, taken alone or in combination, teach or suggest inputting data representative of giving a medical item through an input device adjacent the bed of a patient in the manner recited.

Claim 5

Claim 5 depends from claim 3. Neither of the applied references, taken alone or in combination, teach or suggest inputting data to a computer representative of giving a medical

item to a patient, including reading machine readable indicia with a reading device in the manner recited.

Claim 14

Claim 14 depends from claim 1. Neither of the applied references, taken alone or in combination, teach or suggest generating a report including information indicating that a medical item has been taken for use by, but not yet given, to the patient in the manner recited. Where does Gombrich or Moulding teach or suggest a report indicating that the status of a medical item is intermediate taken and administered?

Claim 15

Claim 15 depends from claim 14. Neither of the applied references, taken alone or in combination, teach or suggest inputting data to a computer responsive to one of a plurality of authorized users; taking a medical item from a storage area by an authorized user; wherein a report generated includes information indicative that the authorized user has taken the medical item for use by the patient, in the manner recited.

Claim 28

Claim 28 depends from claim 16. Neither of the applied references, taken alone or in combination, teach or suggest that generating a report includes operating a printing device to include in the report both machine readable indicia corresponding to a patient and machine readable indicia indicative of a medical item prescribed for the patient. As previously discussed, neither of the applied references teach or suggest generating a report including both machine readable indicia corresponding to a patient and machine readable indicia indicative of a medical

item prescribed for the patient. Nor do the references teach or suggest operating a printing device in generating the report. The Office has not established a *prima facie* showing of obviousness.

The Pending Claims Are Not Obvious Over Gombrich

Claims 9-10 and 19-21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Gombrich. These rejections are respectfully traversed.

Claim 9

Claim 9 depends from claim 7. Neither of the applied references, taken alone or in combination, teach or suggest a bed label attached to a bed of a patient, nor reading machine readable indicia on the bed label with a reading device. The Office has not established a *prima facie* showing of obviousness.

Claim 10

Claim 10 depends from claim 7. Neither of the applied references, taken alone or in combination, teach or suggest reading machine readable indicia on a bedside chart with a terminal reading device in the manner recited.

Claim 19

Gombrich does not teach or suggest the recited features, relationships, and steps. For example, Gombrich does not teach or suggest dispensing a medical item from a medical item dispenser responsive to reading machine readable indicia on a report in inputting to a computer, data corresponding to at least one medical item prescribed for the one patient. Where does Gombrich teach or suggest dispensing a medical item from a medical item dispenser responsive to reading machine readable indicia on a report (step e)? The Action admits (on page 13) that

Gombrich does not teach or suggest "the dispensing of one medical item from a medical item dispenser." The Action further admits (on page 21, last paragraph) that "Gombrich fails to expressly teach a medical item dispenser". Nor does Gombrich teach or suggest a medical item dispenser. Nor has the Action provided a prior art teaching or suggestion of such feature.

It follows that Gombrich cannot teach or suggest dispensing a medical item from a medical item dispenser responsive to reading machine readable indicia, especially where the machine readable indicia is on a report, and further especially where the machine readable indicia is read during inputting data corresponding to at least one medical item prescribed for the one patient to a computer. Nor does Gombrich teach or suggest the other recited steps.

The Action (on page 20) alleges that "the issue at hand is not whether the applied prior art specifically teaches the claimed features, *per se*, but rather, whether or not the prior art, when taken in combination with the knowledge of average skill in the art, would put the artisan in possession of these features". However, the Action lacks a teaching or suggestion of the recited features either in Gombrich or the "prior art". The Action even admits (on pages 13 and 21) that Gombrich fails to teach or suggest the recited features. No other prior art has been applied. However, to have a valid rejection the prior art evidence of record must teach or suggest the recited features. An assertion (as in the Action) of basic knowledge and common sense not based on any evidence in the record lacks substantial evidence support. The Action lacks concrete evidence in the record. *In re Zurko*, supra. The Gombrich reference alone, especially in light of the Action's admitted deficiencies in the reference, cannot be the sole basis for any legally valid rejection.

The only suggestion for having a medical item dispenser (including dispensing a medical item from a medical item dispenser responsive to reading machine readable indicia) is found in Appellants' own novel disclosure. It follows that the alleged modification of Gombrich (and the rejection) is based on hindsight reconstruction of the recited invention based on Appellants' disclosure, which is legally impermissible and does not constitute a valid basis for a finding of obviousness. *In re Fritch*, supra. Therefore, it would not have been obvious to one having ordinary skill in the art to have modified Gombrich to have produced the claimed invention. Nor does Gombrich teach or suggest the recited features and relationships. The Office does not factually support any *prima facie* conclusion of obviousness. Thus, it is respectfully submitted that the 35 U.S.C. § 103(a) rejection should be withdrawn.

Claim 20

Gombrich does not teach or suggest the recited features, relationships, and steps. For example, Gombrich does not teach or suggest storing in a data store, data representative that a medical item has been taken for use by the one patient, responsive to the medical item being dispensed from a medical item dispenser. Gombrich does not associate the dispensing of a medical item from a dispenser with the medical item having been taken for use by a patient. Nor does Gombrich store this information in a data store responsive to the dispensing. Where does Gombrich teach or suggest dispensing a medical item from a medical item dispenser?

Note Appellants' remarks in support of the patentability of claim 19. As previously discussed, Gombrich does not teach or suggest a medical item dispenser. Again, the record lacks substantial evidence support. *In re Zurko*, supra. The Action (on page 14) admits that Gombrich does not even teach or suggest "the dispensing of one medical item from a medical item

dispenser." The Action also admits (on page 21, last paragraph) that "Gombrich fails to expressly teach a medical item dispenser". It follows that Gombrich cannot teach or suggest storing in a data store, data representative that a medical item has been taken for use by the one patient, responsive to the medical item being dispensed from a medical item dispenser. Nor does Gombrich teach or suggest the other recited steps.

The only suggestion for having a medical item dispenser (including storing in a data store, data representative that a medical item has been taken for use by the one patient, responsive to the medical item being dispensed from a medical item dispenser) is found in Appellants' own novel disclosure. It follows that the alleged modification of Gombrich (and the rejection) is based on hindsight reconstruction of the recited invention based on Appellants' disclosure, which is impermissible. *In re Fritch*, supra. Therefore, it would not have been obvious to one having ordinary skill in the art to have modified Gombrich to have produced the claimed invention. Nor does Gombrich teach or suggest the recited features and relationships. Thus, the Office has not established a *prima facie* showing of obviousness.

Claim 21

Claim 21 depends from claim 19. Gombrich further does not teach or suggest dispensing a medical item responsive to the determination that input user data corresponds to an authorized user, and storing in a data store data representative that the medical item has been taken by the authorized user. As previously discussed, even the Action admits that Gombrich does not teach or suggest a medical item dispenser. The Action relies on Gombrich at col. 17, lines 11-14 for comparing user input data to authorized user data. However, where does the relied on section teach comparing a user to an authorized user? Furthermore, where does the relied on section

teach storing data representative that the at least one medical item has been taken by the one authorized user. The relied on section indicates that the drug "remains until" the nurse takes it. That is, how can the relied on section teach storing that a medical item has been taken by the nurse (as alleged) when the nurse has not yet taken the medical item? Again, the Office has not established a *prima facie* case of obviousness.

Additional Comments

Appellants respectfully traverse the comments in the Action at page 23, last paragraph. Appellants have addressed every claim rejection. However, the Office has not established anticipation nor made a *prima facie* showing of obviousness. The Appellants are not required to prove patentability. Contrarily, it is the Office which must establish anticipation or a *prima facie* case of obviousness under the law.

Additionally, the comments are confusing. If no reference is applied which either teaches nor suggests the recited feature, and the Appellants argue such, then what else is there for Appellants to argue? In other words, how can Appellants "point to any specific distinctions" beyond showing that the recited feature isn't even taught or suggested in the prior art? The comments in the Action also misinterpret the meaning of "a general allegation", to which the length of the Supplemental Appeal Brief can attest. The Action's allegation that the Appellants failed to address the issues is a further example of the Office's unfair interpretation of the issues and is reflective of the impropriety of all the rejections on appeal.

CONCLUSION

Each of Appellants' pending claims specifically recites features and relationships that are neither disclosed nor suggested in any of the applied art. Furthermore, the applied art is devoid of any teaching, suggestion, or motivation for combining features of the applied art so as to produce the recited invention. For these reasons it is respectfully submitted that all the pending claims are allowable.

Respectfully submitted,

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#14

REVISED APPENDIX

CLAIMS

1. A method comprising the steps of:

(a) storing in a data store in operative connection with a computer, data representative of a plurality of patients for whom medical items may be used;

(b) generating a report, wherein the report includes machine readable indicia corresponding to at least one of the patients and machine readable indicia corresponding to at least one item prescribed for the patient;

(c) reading the machine readable indicia on the report corresponding to a patient with a reading device;

(d) inputting to the computer, data representative of a medical item, wherein the computer is operative to include in the data store, data representative of the taking of the medical item for use by the patient;

(e) inputting data to the computer representative of giving the medical item to the patient, wherein the computer is operative to include in the data store, data representative of the medical item having been given to the patient.

2. The method according to claim 1 wherein step (a) further comprises storing in the data store, data representative of medical items prescribed for each patient, and wherein step (d) comprises reading the machine readable indicia corresponding to the medical item with the reading device.

3. The method according to claim 1 wherein step (e) further comprises inputting the data representative of giving the medical item through an input device adjacent the bed of the patient.

4. A method comprising:

(a) storing in a data store in operative connection with a computer, data representative of a plurality of patients for whom medical items may be used;

(b) generating a report, wherein the report includes machine readable indicia corresponding to at least one of the patients;

(c) reading the machine readable indicia on the report corresponding to a patient with a reading device;

(d) inputting to the computer, data representative of a medical item, wherein the computer is operative to include in the data store, data representative of the taking of the medical item for use by the patient;

(e) inputting data representative of giving the medical item to the patient to a portable terminal, storing data representative of the giving of the medical item to the patient in the portable terminal, and transferring data representative of the giving of the medical item to the patient from the portable terminal to the computer, wherein the computer is operative to include in the data store, data representative of the medical item having been given to the patient.

5. The method according to claim 3 wherein step (e) further comprises reading machine readable indicia with a reading device.

6. The method according to claim 4 wherein the portable terminal includes a terminal reading device, and wherein in step (e) the inputting of the data representative of giving the medical item includes reading machine readable indicia with the terminal reading device.

7. The method according to claim 6 and prior to step (e) further comprising:

labeling a patient associated item in proximity to the patient with machine readable indicia corresponding to the patient;

and wherein step (e) includes reading the machine readable indicia on the patient associated item with the terminal reading device.

8. The method according to claim 7 wherein the patient associated item includes a band attached to the patient, and wherein step (e) includes reading machine readable indicia on the band with the terminal reading device.

9. The method according to claim 7 wherein the patient associated item includes a bed label attached to a bed of the patient, and wherein step (e) includes reading the machine readable indicia on the bed label with the terminal reading device.

10. The method according to claim 7 wherein the patient associated item includes a bedside chart, and wherein step (e) includes reading the machine readable indicia on the bedside chart with the terminal reading device.

11. The method according to claim 7 wherein step (a) further comprises storing in a data store, data representative of medical items prescribed for the patient, and wherein prior to step (e) the method further comprises generating a prescribed item report with a report generating device, wherein the prescribed item report includes machine readable indicia corresponding to at least

one medical item prescribed for the patient, and wherein step (e) includes reading the machine readable indicia corresponding to the medical item from the prescribed item report.

12. The method according to claim 7 wherein step (a) further comprises storing in the data store, data representative of medical items prescribed for the patient, and step (b) further comprises including in the report, machine readable indicia corresponding to at least one medical item prescribed for the patient, and wherein step (e) comprises reading machine readable indicia on the report with the terminal reading device.

13. The method according to claim 4 wherein a docking port is in operative connection with the computer, wherein the portable terminal is operative to communicate with the computer through the docking port, and wherein step (e) includes placing the portable terminal in connection with the docking port, wherein the data representative of the giving of the medical item is transferred from the portable terminal to the computer through the docking port.

14. The method according to claim 1 and prior to step (e) further comprising the step of:

(f) generating a report responsive to data in the data store, the report including information indicating that the medical item has been taken for use by, but not yet given, to the patient.

15. The method according to claim 14 and prior to step (f) further comprising the steps of:

storing in the data store, data representative of a plurality of authorized users;

inputting data to the computer responsive to one of the plurality of authorized users;

taking the medical item from a storage area, wherein the medical item is taken by the authorized user;

wherein the report generated in step (f) includes information indicative that the authorized user has taken the medical item for use by the patient.

16. A method comprising the steps of:

(a) storing in a data store in operative connection with a computer, data representative of a plurality of patients for whom medical items may be used;

(b) storing in the data store, data representative of a plurality of medical items prescribed for use by corresponding patients;

(c) generating a report including machine readable indicia indicative of a medical item prescribed for a patient, wherein the report further includes information indicative of the patient;

(d) inputting to the computer, data corresponding to one of the plurality of patients;

(e) inputting to the computer, data corresponding to at least one medical item indicated by data in the data store as prescribed for the one patient, including reading with a reading device the machine readable indicia on the report;

(f) storing in the data store, data representative that the at least one medical item has been taken for use by the one patient;

(g) using the at least one medical item in the medical treatment of the one patient; and

(h) inputting data to the computer indicative that the at least one medical item has been used in the medical treatment of the one patient, wherein the computer is operative to include in the data store, data representative that

the at least one medical item has been used in the medical treatment of the one patient.

17. The method according to claim 16 and prior to step (d) comprising including on the report, machine readable indicia indicative of the one patient, and wherein step (d) comprises reading with a reading device the machine readable indicia indicative of the one patient on the report.

18. The method according to claim 16 wherein step (h) comprises inputting the data representative that at least one medical item has been used in the medical treatment of the one patient to a portable terminal, storing data representative that the at least one medical item has been used in the medical treatment of the one patient in the portable terminal, and transferring data representative that the at least one medical item has been used in the medical treatment of the one patient from the portable terminal to the computer.

19. A method comprising:

(a) storing in a data store in operative connection with a computer, data representative of a plurality of patients for whom medical items may be used;

(b) storing in the data store, data representative of a plurality of medical items prescribed for use by corresponding patients;

(c) inputting to the computer, data corresponding to one of the plurality of patients;

(d) inputting to the computer, data corresponding to at least one medical item prescribed for the one patient;

(e) dispensing the at least one medical item from a medical item dispenser responsive to reading machine readable indicia on a report in step (d).

20. A method comprising:

(a) storing in a data store in operative connection with a computer, data representative of a plurality of patients for whom medical items may be used;

(b) storing in the data store, data representative of a plurality of medical items prescribed for use by corresponding patients;

(c) inputting to the computer, data corresponding to one of the plurality of patients;

(d) inputting to the computer, data corresponding to at least one medical item prescribed for the one patient;

(e) storing in the data store, data representative that the at least one medical item has been taken for use by the one patient, responsive to the at least one medical item being dispensed from a medical item dispenser;

(f) using the at least one medical item in the medical treatment of the one patient; and

(g) inputting data to the computer indicative that the at least one medical item has been used in the medical treatment of the one patient, wherein the computer is operative to include in the data store, data representative that the at least one medical item has been used in the medical treatment of the one patient.

21. The method according to claim 19 and prior to the dispensing step, further comprising the steps of:

storing in the data store, data representative of a plurality of authorized users;

inputting to the computer, user data;

comparing the input user data to the data stored concerning authorized users and determining that the input user data corresponds to one authorized user;

wherein the step of dispensing the at least one medical item is carried out responsive to the determination that the input user data corresponds to one authorized user, and further comprising storing in the data store data representative that the at least one medical item has been taken by the one authorized user.

22. The method according to claim 16 wherein step (h) comprises storing data in a portable terminal adjacent a bedside of the patient indicative that the at least one medical item has been used in the medical treatment of the one patient, and thereafter placing the portable terminal in operative connection with the computer, wherein information indicative of the use of the at least one medical item in the treatment of the patient is passed from the portable terminal to the computer.

23. The method according to claim 22 wherein step (h) further comprises reading machine readable indicia on a patient associated item in proximity to the patient with a terminal reading

device in operative connection with the portable terminal, wherein the data indicative that the at least one medical item has been given to the patient is stored in the portable terminal responsive to reading the machine readable indicia on the patient associated item.

24. The method according to claim 23 wherein in step (h) the patient associated item from which the machine readable indicia is read comprises at least one of a band worn by the patient, a bed label or a chart.

25. The method according to claim 16 and further comprising the step of storing data in a bedside terminal adjacent the one patient, indicative that the one medical item has been used in the medical treatment of the one patient.

26. A method comprising:

(a) storing in a data store in operative connection with a computer, data representative of a plurality of patients for whom medical items may be used;

(b) storing in the data store, data representative of a plurality of medical items prescribed for use by corresponding patients;

(c) inputting to the computer, data corresponding to one of the plurality of patients;

(d) inputting to the computer, data corresponding to at least one medical item prescribed for the one patient;

(e) storing in the data store, data representative that the at least one medical item has been taken for use by the one patient;

(f) using the at least one medical item in the medical treatment of the one patient; and

(g) storing data in a bedside terminal positioned in generally fixed relation adjacent a bedside area of the one patient, indicative that the at least one medical item has been used in the medical treatment of the one patient.

27. The method according to claim 26 and further comprising storing data in a portable terminal adjacent a bedside of the patient indicative that the at least one medical item has been used in the medical treatment of the one patient, wherein step (g) includes passing the data between the portable terminal and the bedside terminal.

28. The method according to claim 16 wherein generating the report includes operating a printing device to include in the report both machine readable indicia corresponding to a patient and machine readable indicia indicative of a medical item prescribed for the patient.